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510(k) SUMMARY

Inion® CPS/OTPS FreedomPlate™

JAN 23 2007

Indications for use

A. General indications: In the presence of appropriate additional immobilization or fixation, indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures, and cement restriction in total joint arthroplasty procedures.

B. Specific indications:
1. Craniofacial skeleton, cranium, mid-face, maxilla, and mandible
2. Metacarpus, proximal and middle phalangeal bones
3. Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax

Substantial equivalence to marketed products

Based on the performance data and specifications presented, it can be concluded that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion CPS/OTPS FreedomPlate™ are substantially equivalent with the predicate devices Inion® CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352), Inion® OTPS™ Biodegradable Mini Plating System (K023887) and Inion® OTPS™ Biodegradable Mesh Plating System (K031961).

Inion CPS/OTPS FreedomPlate™ is substantially equivalent to predicate Class II devices, when used, in the presence of appropriate additional immobilization or fixation, for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures, and cement restriction in total joint arthroplasty procedures, because the differences between Inion CPS/OTPS FreedomPlate™ and the predicate devices do not raise new questions of safety and effectiveness.

510(k) SUMMARY

Inion® CPS/OTPS FreedomPlate™

Manufacturer and submitter
Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person
Kati Marttinen, Regulatory Affairs Specialist
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kati.marttinen@inion.com

Establishment registration number
9710629

Trade name of the device
Inion® CPS/OTPS FreedomPlate™

Device classification and product code
Class II
Classification Panel: Orthopedic
Product Code: HRS
Common name: Plate, fixation, bone
Regulation number: 21 CFR 888.3030

Predicate devices
Inion® CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352)
Inion® OTPS™ Biodegradable Mini Plating System (K023887)
Inion® OTPS™ Biodegradable Mesh Plating System (K031961)

Conformance with performance standards
No applicable mandatory performance standards exist for this device.
Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

Inion CPS/OTPS FreedomPlate™ implants are made of resorbable polylactic acid / trimethylenecarbonate copolymers and they are provided in sizes typical to this application. Inion CPS/OTPS FreedomPlate™ implants gradually lose their strength during 18-36 weeks in vivo. Bioresorption takes place within two to four years.

Inion CPS/OTPS FreedomPlate™ implants are provided sterile to the user. The shelf life of the device is 3 years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Inion Oy
% Ms. Kati Marttinen
Regulatory Affairs Specialist
L¨a¨ak¨arinkatu 2
33520 Tampere, FINLAND

JAN 2 3 2007

Re: K063410
Trade/Device Name: Inion® CPS/OTPS Freedom Plate™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 10, 2006
Received: November 13, 2006

Dear Ms. Marttinen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K063410

Device Name: Inion® CPS/OTPS FreedomPlate™

INDICATIONS

A. General indications: In the presence of appropriate additional immobilization or fixation, indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures, and cement restriction in total joint arthroplasty procedures.

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3. Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of General, Restorative, and Neurological Devices

510(k) Number K063410